

### **REMARKS**

Reconsideration and withdrawal of the rejections of the Office Action are respectfully requested in view of the remarks and accompanying information herein.

Examiner Mosher is kindly thanked for the many courtesies extended during the personal interview of July 13, 2009, and for indicating that the rejections under 35 U.S.C. §102, as well as under 35 U.S.C. §103 in part, have been withdrawn.

### **I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1, 6, 10-22, and 31 are currently pending. Claims 1 and 6 have been amended, and claims 5 and 30 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

Support for the amendment to claim 1 can be found, in the original specification on page 4, lines 14-17, and in the paragraph bridging pages 21 and 22, and in former claims 5 and 30. The amendment to claim 6 perfects antecedent basis. No new matter is added.

It is respectfully submitted that the claims herewith and as previously pending are and were patentably distinct from the references cited by the Examiner, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations are found throughout the specification and in the originally claims as originally filed.

### **II. THE SECTION 103 ART REJECTIONS ARE OVERCOME**

Claims 1, 5, 6, 10-13, 15-18, 20, 30, and 31 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined teaching of Paoletti et al. (U.S. Patent No. 5,744,141; hereinafter "Paoletti (a)"), Chang (U.S. Patent Publication No. 2003/0022849), and Paoletti (b) (U.S. Patent No. 5,505,941; hereinafter "Paoletti (b)"). Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined teaching of Paoletti (a), Chang, Paoletti (b), and Ramshaw et al. (Immunol Today, 2000, 21: 163-165). Further claims 14 and 19 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable

over the combined teaching of Paoletti (a), Chang, Paoletti (b), and Audonnet et al. (WO 99/44633). These rejections are traversed and will be addressed collectively.

Applicants respectfully remind that the Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727. Furthermore, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applying the law to the instant facts, the references relied upon by the Office Action do not render the presently claimed invention obvious. The skilled artisan would recognize that Paoletti (a), at most, suggests that the protective effects of proteins of one species of flavivirus in a recombinant poxvirus cannot be transposed to other species of flavivirus. For example, in Example 9 of Paoletti (a), recombinant vaccinia virus vP825, which encoded JEV proteins C, prM, E, NS1, and NS2, induced protection against JEV challenge (*see* Table 4; 9/10 survived after double immunization). On the other hand, in Example 11 of Paoletti (a), recombinant vaccinia virus vP766, which encoded the same proteins but for Yellow Fever, did not induce protection against YF challenge (*see* Table 8; 0/16 survived after double immunization). Hence, these results indicate that the skilled artisan cannot consider the protective effects of recombinant poxviruses encoding JEV proteins and predict that recombinant poxviruses, or recombinant canarypox viruses in particular, encoding other flavivirus proteins will have the same protective effect.

The skilled artisan would also consider that Chang teaches away from using a recombinant canarypox virus encoding West Nile Virus (WNV) prM, M, and E proteins. In Example 11 of Chang, while naked DNA encoding prM, M, and E induced a protective response in vaccinated mice, the vaccinated mouse sera reacted only with E protein in a Western blot analysis (Chang, col. 31, lines 64-65). This suggests to the skilled artisan that only the E protein is present and thereby the only protein necessary to induce a protective response against viral challenge. Thus, the skilled artisan would be deterred from using a recombinant virus encoding all of WNV prM, M, and E.

Finally, the skilled artisan would consider that Paoletti (b) is silent as to flaviviruses, and would recognize that the results concerning rabies and influenza viruses depicted in the Examples of Paoletti (b) are not transposable to flaviviruses.

Therefore, the skilled artisan would not predict that the claimed invention can be successfully obtained by combining the cited references. The skilled artisan would have to:

(1) accept that the results obtained for recombinant vaccinia virus encoding JEV or YF proteins can apply to West Nile Virus, despite that Paoletti (a) shows that the protective effects of recombinant poxviruses encoding flavivirus proteins are unpredictable; then

(2) accept that the results obtained from using naked DNA encoding WNV prM, M, and E can apply to recombinant poxviruses, despite that Chang suggests only encoding WNV E is necessary; and then

(3) accept that the results obtained from (1) and (2) can be obtained by switching from recombinant vaccinia virus to recombinant canarypox virus, despite that Paoletti (b) only demonstrates recombinant avipox viruses encoding rabies and influenza proteins, and not WNV or even flaviviral proteins.

Importantly, neither Ramshaw et al. nor Audonnet et al. remedies the deficiencies in Paoletti (a), Chang, and Paoletti (b). Ramshaw et al. relates to prime-boost regimens, including priming with DNA vaccines and boosting with an attenuated virus, while Audonnet et al. relates to recombinant live vaccines comprising a viral vector that expresses a heterologous gene, and an adjuvant from the carbomer class of compounds. Neither suggests that the claimed invention can be successfully obtained.

In addition, the claimed invention demonstrates surprising results. Firstly, administration of the instantly claimed vaccine composition induced both an immune and protective response in

horses (*see*, Examples 24 and 25, respectively) as well as cats (*see*, Examples 26 and 27, respectively). Unexpectedly, even a single dose of the claimed vaccine composition induced protection against challenge (*see*, Example 32). None of the cited references, individually or combined, could predict such results stemming from vaccination with a vector comprising a recombinant canarypox virus that encodes and expresses *in vivo* in the animal WNV polypeptide prM-M-E.

Moreover, the claimed invention has experienced commercial success as a product. Applicants refer to the Declaration under 37 C.F.R. § 1.132 by Bob Nordgren, Head of Global Biologics R&D at Merial Limited, which is the assignee. The Declaration indicates that the claimed invention, marketed as RECOMBITEK® Equine West Nile Virus Vaccine, has commanded a substantial share of the market for equine vaccines against WNV since its launch. The number of WNV equine infections has simultaneously lowered over the same period. The claimed vaccine was and is the only vaccine that has been demonstrated to protect against natural mosquito borne challenge. The vaccine also has been shown to protect against disease as well as infection. Therefore, the claimed invention has succeeded as a commercial product.

For all of the reasons described above, the cited references do not render the claimed invention obvious. Consequently, Applicants request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

### **III. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME**

Claims 1, 5, 6, 10-22, 30, and 31 were provisionally rejected on the basis of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-28 of copending U.S. application Serial No. 10/679,520. The rejection is respectfully traversed.

Applicants thank the Examiner for previously acknowledging that Applicants will address this rejection upon a determination of allowable subject matter in either the present application or USSN 10/679,520, and for noting that the present application is the later-filed application.